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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,229	04/06/2007	Vasso Apostolopoulos	3489-103	1201

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EXAMINER

CHONG, KIMBERLY

ART UNIT	PAPER NUMBER
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1635

NOTIFICATION DATE	DELIVERY MODE
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08/08/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No. 10/579,229	Applicant(s) APOSTOLOPOULOS ET AL.	
	Examiner KIMBERLY CHONG	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-49 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. Furthermore, under PCT Rule 13.2 the requirement of unity of invention referred to in PCT Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-14, 18-20, drawn to a compound comprising a conjugate of a polynucleotide or oligonucleotide molecule, a carrier comprising at least one aldehyde group and optionally a suitable linker molecule conjugating said polynucleotide or oligonucleotide with said carrier, wherein said carrier is hormone. **This group is subject to species elections as per below.**

Group II, claim(s) 1-14, 18-20, drawn to a compound comprising a conjugate of a polynucleotide or oligonucleotide molecule, a carrier comprising at least one aldehyde group and optionally a suitable linker molecule conjugating said polynucleotide or

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oligonucleotide with said carrier, wherein said carrier is an enzyme. **This group is subject to species elections as per below.**

Group III, claim(s) 1-14, 18-20, drawn to a compound comprising a conjugate of a polynucleotide or oligonucleotide molecule, a carrier comprising at least one aldehyde group and optionally a suitable linker molecule conjugating said polynucleotide or oligonucleotide with said carrier, wherein said carrier is a cytokine. **This group is subject to species elections as per below.**

Group IV, claim(s) 1-20, drawn to a compound comprising a conjugate of a polynucleotide or oligonucleotide molecule, a carrier comprising at least one aldehyde group and optionally a suitable linker molecule conjugating said polynucleotide or oligonucleotide with said carrier, wherein said carrier is a carbohydrate polymer such as oxidized mannan. **This group is subject to species elections as per below.**

Group V, claim(s) 38-49, drawn to a compound comprising a conjugate of a polynucleotide or oligonucleotide molecule, a carrier comprising at least one aldehyde group and optionally a suitable linker molecule conjugating said polynucleotide or oligonucleotide with said carrier, wherein said carrier is reduced mannan. **This group is subject to species elections as per below.**

Group VI, claim(s) 21, drawn to a method for cell-specific delivery of a polynucleotide or oligonucleotide molecule to a target cell of a subject comprising administering the compounds listed in claims 1-20.

Group VII, claim(s) 22-27, drawn to a method for inducing an immune response to an antigen or epitope wherein said immune response is primarily a CD8⁺ type of

immune response wherein the carrier is a hormone. **This group is subject to species elections as per below.**

Group VIII, claim(s) 22-27, drawn to a method for inducing an immune response to an antigen or epitope wherein said immune response is primarily a CD8+ type of immune response wherein the carrier is an enzyme. **This group is subject to species elections as per below.**

Group IX, claim(s) 22-27, drawn to a method for inducing an immune response to an antigen or epitope wherein said immune response is primarily a CD8+ type of immune response wherein the carrier is a cytokine. **This group is subject to species elections as per below.**

Group X, claim(s) 22-30, drawn to a method for inducing an immune response to an antigen or epitope wherein said immune response is primarily a CD8+ type of immune response wherein the carrier is a carbohydrate polymer. **This group is subject to species elections as per below.**

Group XI, claim(s) 31-37, drawn to a method for inducing an immune response to an antigen or epitope wherein said immune response is primarily a CD8+ type of immune response. **This group is subject to species elections as per below.**

The inventions listed as Group I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reason: the special technical feature of groups I-VII is an compound comprising a polynucleotide and a carrier. The

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compound cannot be a special technical feature under PCT Rule 13.2 because the element is shown in the prior art. Sasaki et al. teach a complex comprising a DNA and a carrier mannan (see abstract and pages 3121-3129). Therefore, unity of invention is lacking.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Claims 7-8, 36-37 and 43-45 are drawn to protein or peptides of an antigen, a polypeptide, an enzyme or a hormone. Each of the proteins or peptides is distinct from each other because they each have a distinct structure and function and one (1) must be elected. The search and examination of each targeted protein or peptides is burdensome because the searches are not coextensive.

Claims 9 and 46 are drawn to specifically named compounds of antisense RNA, catalytic RNA or siRNA. Each compound is distinct from the other because each has a different nucleic acid sequence and structure and one (1) must be elected. The search and examination of each compound is burdensome because the searches are not coextensive.

Claims 19-20 and 48-49 are drawn to specifically named linkers selected from a polycation linker, PLL, PEI, dendrimers or cationic lipids. Each of the linkers are distinct from each other because each comprises a distinct structure and each has a different

biological activity from the other and one (1) must be elected. The search and examination for each of the linkers is burdensome because the searches are not coextensive.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record

showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Friday between 7-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached at 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Kimberly Chong/
Examiner
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